



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,725	02/27/2004	Hea Young Park Choo	DE-1557	9620
1109 7590 06/07/2007 ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK,, NY 10020-1182			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			06/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,725	Applicant(s) PARK CHOO ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment filed March 21, 2007 is acknowledged. Claims 1-7 and 10 remain under consideration.

An Information Disclosure Statement filed March 21, 2007 is acknowledged. Every cited reference on form 1449 must include an author's name and publication (i.e., journal) source.

A Declaration under 37 CFR 1.132 by Hea Young Park Choo filed March 21, 2007 is further acknowledged.

Claims 2 and 3 were rejected under 35 U.S.C. § 112, first paragraph, in the last Office Action because the specification, while being enabling for the inhibition of 5-lipoxygenase activity, does not reasonably provide enablement for treatment regimens as recited in claims 2 and 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification provides no support for treating the specific disease states recited in claim 2, comprising administering a compound of instant formula I.

Applicants argue the new Declaration under 37 CFR 1.132 demonstrates the therapeutic effect of treating asthma comprising administering the compound of Example 9 of the subject application.

Applicants' argument and Declaration are persuasive. The compound of Example 9 in a method of treating asthma would be given favorable consideration. Additionally, because the Declaration shows 1) the administration of said compound in an *in vivo* mice model results in low airway hyperresponsiveness, as compared to the

Art Unit: 1614

leukotriene inhibitor zileuton, when challenged by ovalbumin; 2) improved inhibition of the cytokines IL-4, IL-5 and IL-13, as compared to zileuton, in bronchoalveolar lavage fluid; and 3) a suppressive effect on leukocyte infiltration in mouse lung tissue, it would have been reasonable to expect other pulmonary pathologies, such as cystic fibrosis, acute/chronic bronchitis, pertussis and allergic rhinitis, would have been favorably treated by the administration of the compound of Example 9.

However, the showing is not commensurate in scope with the claimed subject matter. The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant methods of treating any leukotriene-related disease with any compound of instant formula I without resorting to undue experimentation. Inhibition of 5-lipoxygenase affects diverse organ systems in an unpredictable manner. Each particular type of pathology characterized by 5-lipoxygenase activity has its own specific characteristics and etiology. A successful treatment modality for one of the recited disease states does not presage success for preventing that same disease.

The rejection of claims 2 and 3 of record under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and presently extended to include claims 1, 4-7 and 10.

In the last Office Action claims 1, 2, 6 and 7 were rejected under 35 U.S.C. 102(b) as being anticipated by Elnima et al., Antimicrobial Agents and Chemotherapy.

Applicants have amended the compounds of instant formula I such that Y is sulfur when R² is (ii) or (iv) in claim 1.

Accordingly, the rejection of record under 35 U.S.C. 102(b) is withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elnima et al., Antimicrobial Agents and Chemotherapy.

Elnima teaches the administration of various benzoxazole derivatives that exhibit antibacterial and antifungal activities. Such activities are septic activities, i.e., they relate to the presence of pathogenic organisms or their toxins in the blood or tissues. See page 30, compounds III, V and VI, wherein the depicted R groups are among those encompassed by the instant R² group of instant formula I. The claims differ in that a sulfur atom replaces an oxygen atom, i.e., benzoxazole versus benzothiazole.

Such compounds are ring analogs and would reasonably be expected to exhibit similar chemical and physical properties. See *In re Payne*, 203 USPQ 245 (CCPA 1979).

Further, basic truths of nature cannot be owned. In view of Elnima's teaching, both benzoxazole and analogous benzothiazole derivatives inherently inhibit 5-lipoxygenase activity.

The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 1254, 195 USPQ 430, 433 (CCPA 1977).

No claim is allowed.

It is noted claims 1-7 and 10 provisionally conflict with claims 5-7 of copending Application No. 11/549280. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application are drawn to methods of treating leukotriene-related diseases comprising administering compounds of instant formula I.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any

Art Unit: 1614

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 4, 2007


Phyllis G. Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER